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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/525,797	03/15/2000	Athanasius A Anagnostou	5218-39B	9917

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EXAMINER	
UNGAR, SUSAN NMN	

ART UNIT	PAPER NUMBER
1642	18

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/525,797	ANAGNOSTOU ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *22 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *12-15,19-21 and 23-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *12-15,19-21 and 23-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/22/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission Information Disclosure, filed on September 22, 2003 has been entered. Claims 12-15, 19-21 and 23-26 are currently under prosecution.

2. The text of those Sections Title 35, USC. Code not included in this action can be found in a prior Office action.

Double Patenting

3. The non-statutory double patenting rejection, whether of the obviousness type or non-obviousness type, is based on a judicially created doctrine grounded in public policy (a policy relected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 438, 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed b the assignee must fully comply with 37 CFR 3.73(b)

Claims 12-15, 19-21, 223-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 31-32, 35-38 and 40 of Application No. 09/525,808.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they relate to the same inventive concept. The instant claims read on the copending claims and would be obvious over those claims which are drawn to a method of treating endothelial injury in a subject comprising administering an effective endothelial-protecting amount of erythropoietin to said subject in need of such treatment wherein said endothelial injury is caused by cisplatin. Since it is known in the art that cisplatin is used only to treat solid tumors which must be vascularized, since the method steps of the claims of the copending application comprise the same method steps as the instant application, that is administering EPO prior to, concurrent with and after CIS to the same population, it would be expected that the method of the copending application would treat a solid vascularized tumor in a subject and the instant claims are obvious over the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 12, 19, 26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 6-7 of US Patent No. 5, 922, 674. Although the conflicting claims are not identical, they are not patentably distinct from each other because they relate to the same inventive concept. The instant claims are species of the claims of the copending application and would have been obvious in view of the copending claims which have all of the characteristics of a method of treating a solid vascularized tumor in

a subject in need of treatment comprising administering a platinum coordination complex therapeutic agent in conjunction with EPO wherein said EPO is administered in an amount effective to enhance suppression of endothelial growth associated with administration of said cisplatin. Examiner takes not e that cisplatin is a chemotherapeutic platinum coordination complex conventionally used to treat solid vascularized tumors and that cisplatin is conventionally administered intravenously. Although the patent claims are drawn to a method of inhibiting endothelial cell proliferation in a subject treated with a platinum coordination complex, given the above, it is prima facie obvious to treat with conventionally used cisplatin.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 12, 19, 20, 26 are rejected under 35 USC 102(b) as being anticipated by Bukowski et al, (Blood, 84, No. 1, Suppl. 1, 129a, 1994), IDS Item.

The claims are drawn to a method of treating a solid vascularized tumor in a subject in need of such treatment comprising administering cisplatin in conjunction with erythropoietin wherein said erythropoietin is administered in an amount effective to enhance suppression of endothelial

growth associated with administration of cisplatin (claims 12), wherein the cisplatin is administered iv (claims 19 and 26), wherein said EPO is administered iv (claim 20).

Bukowski et al teach a successful phase IV study wherein EPO was administered sc to 441 cancer patients in conjunction with cisplatin, wherein improvement in quality of life parameters was found wherein the patients experienced improved energy level, activity level and overall well-being, wherein transfusion requirements were reduced. The method of the prior art comprises the same method steps as claimed in the instant invention, that is administering EPO in conjunction with CIS to the same population, that is patients with solid vascularized tumors, thus the same method is anticipated because the method will inherently lead to the enhanced suppression of endothelial growth associated with the administration of cisplatin. See Ex parte Novitski 26 USPQ 1389 (BPAI 1993). Further, Examiner takes note that both cisplatin and EPO are conventionally administered intravenously.

7. Claims 12, 15, 19, 20, 21, 24-26 are rejected under 35 USC 102(b) as being anticipated by JP 02 096535, IDS item.

The claims are drawn to a method of treating a solid vascularized tumor in a subject in need of such treatment comprising administering cisplatin in conjunction with erythropoietin wherein said erythropoietin is administered in an amount effective to enhance suppression of endothelial growth associated with administration of cisplatin (claims 12), wherein the EPO is administered after the cisplatin (claim 15), wherein the cisplatin is administered iv (claims 19 and 26), wherein said EPO is administered iv

(claim 20), wherein the EPO is administered in a range of 750 units/kg (claim 21), wherein the cisplatin is administered intravenously (claim 24), wherein the EPO is administered intravenously (claim 25).

JP 02 096535 teaches a method of reducing the side effects of cisplatin administration in patients with solid vascularized cancers, wherein the dose of human EPO is 500-100000 U/Day (which is within the range claimed for a subject up to 133 pounds, wherein the EPO is administered intravenously (see abstract), to a subject with a solid vascularized tumor in need of such treatment comprising administering cisplatin in conjunction with erythropoietin, wherein the erythropoietin is administered after the cisplatin. The method of the prior art comprises the same method steps as claimed in the instant invention, that is, administering EPO in conjunction with CIS to the same population, that is patients with solid vascularized tumors, thus the claimed methods id anticipated because the method will inherently lead to the enhanced suppression of endothelial growth associated with administration of cisplatin. See Ex parte Novitski 26 USPQ 1389 (BPAI 1993). Further, Examiner takes note that both cisplatin and EPO are conventionally administered intravenously.

8. No claims allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvette Eyler, can be reached at 571-272-0871 The fax phone number for this Art Unit is (703) 305-7230.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
March 8, 2004